Remarks

Applicants have amended Claim 1 to clarify that the substrate that the substrate is cylindrical and made of metal and that the exterior surface of the metal substrate is also a metal exterior surface. Claim 1 has also been amended to clarify that the stent-forming metal is deposited onto the metal exterior surface of the metal substrate, and that the stent is defined in the deposited metal on the exterior surface of the cylindrical substrate. Claim 11 has been amended to clarify that the heterogeneities that are controlled are at the surface of the biocompatible material.

I. Applicant's Information Disclosure Statement Filed January 30, 2002 was timely filed must be considered by the Examiner

Applicant hand-filed an Information Disclosure Statement on January 30, 2002, which has, to-date, not been considered by the Examiner. During a telephone conference with the Examiner on January 8, 2003, the Examiner searched the Office records and learned that the entire Information Disclosure Statement was, received by the Office, but that due to its volume, was separated by the Office into two boxes.

As the Information Disclosure Statement was timely filed pursuant to 37 C.F.R. 1.97, and has been confirmed by the Examiner to be complete, Applicant submits that it is incumbent on the Examiner to consider all of the cited references filed in the Information Disclosure Statement of January 30, 2002 in the course of further examination of this application.

II. The rejection of Claims 1-8 and 10-26 under 35 U.S.C. 102 over Clubb, et al. (U.S. Patent No. 6,203,732) is moot in view of the amendments presented herein and should be withdrawn.

Anticipation under 35 U.S.C. §102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999). The rejection under 35 U.S.C.

§102(e) in view of Clubb, et al. is improper because the reference fails to disclose each element of the claims and, therefore, fails to anticipate the claimed invention.

Clubb, et al is cited as allegedly disclosing a method of manufacturing a stent comprising providing a substrate having a continuously curved exterior surface, vacuum depositing a metal onto the substrate, forming a plurality of interconnected structural elements and removing the substrate. With regard to Claims 20-21 and 23-26, the Examiner has erroneously cited Clubb as disclosing "control of heterogeneities and by controlling the type of material used during deposition, properties such as grain size, phase, material composition, binding sites, strength, etc. are inherently controlled," referring to Col. 5, lines 10-25.

Applicant has amended base claims 1 and 11 to patentably distinguish over Clubb, et al. Specifically, Claim 1 now requires that the substrate have a metal exterior surface onto which the stent-forming metal is deposited. As acknowledged by the Examiner, Clubb, et al teaches employing a photoresist layer 16 on the exterior surface of the substrate. The photoresist layer 16 is then etched to define a series of depressions within the substrate surface that define the stent pattern. In Clubb, et al. the stent-forming metal is then deposited by vacuum deposition onto the patterned substrate (See Fig. 14), then the undesired deposited metal 20 is machined away (Fig. 16 and Col. 4, lines 44-53), to leave the deposited metal filing the pattern of depressions in the substrate.

In sharp contrast to the method of Clubb, et al., the presently claimed method provides an unpatterned, cylindrical metal substrate having a metal exterior surface. In the present invention there is no patterning of the substrate, and, hence, the need for the photoresist coating 16 of Clubb, et al is eliminated. In the presently claimed invention, the stent-forming metal is deposited directly onto the metal exterior surface. In further contrast to Clubb, et al, the step of forming the stent pattern is a step that is separate from that of depositing the stent-forming metal. In Clubb, et al, the stent pattern is formed during the deposition process, rather than as a separate method step. Thus, in Clubb, et al. the stent pattern is actually defined prior to the deposition step by etching the photoresist and the underlying regions of the substrate, yet the actual stent structural members are inherently defined during the deposition of the stent-forming metal, not as a step separate from the depositing step.

Notably, the Examiner's rejection of Claim 11 fails to address step (b), specifically the sub-step of controlling the formation of heterogeneities in surfaces of the biocompatible material during deposition. Accordingly, with regard to Claim 11, at least, the Examiner's §102(e) rejection is inappropriate.

Finally, with regard to Claims 20-21 and 23-26, the Examiner relies upon the teaching of Clubb, et al at Col. 5, lines 10-25. A careful reading of this disclosure, however, fails to reveal that Clubb, et al makes any type of teaching that the deposition process may be controlled to control heterogeneities at the surface of the deposited biocompatible material as claimed in the present application. At most, Clubb, et al suggests that by varying the depth of the depressed pattern in the substrate, the resulting thickness of the stent structural members may be varied, that the stent material may "tantalum, niobium, zirconium, titanium or platinum vapor applied on a stainless steel mandrel", and that a radiopaque layer may be vacuum deposited between two layers of other materials. Clubb, et al however makes no explicit teaching of how to control these factors during the practicing of the method, nor does Clubb, et al teach that that these factors are heterogeneities or that there is any motivation in the reference to control their formation at surfaces of the biocompatible material.

Accordingly, Applicants submit that the present claims traverse the rejection under §102(e) as allegedly being anticipated by Clubb, et al.

III. The rejection of 11 and 14-26 under 35 U.S.C. 102 over Roth (U.S. Patent No. 6,069,175) is inapplicable to the amended claims and should be withdrawn.

Applicants respectfully submit that the Examiner has again incorrectly relied upon Roth as disclosing all the elements under 35 U.S.C. §102(e) of independent claim 11 or of the claims depending from claim 11. Amended claim 11 requires in step (b) that heterogeneities be controlled in the surfaces of the biocompatible material during deposition. The Examiner's rejection of Claim 11 is notably silent on any comparable step in the Roth reference. The Examiner bare assertion in connection with the rejection of claims 20-21 and 23-26 that "by controlling the type of material used during deposition, properties such as grain size, phase,

material composition, binding sites, strength, etc. are inherently controlled" is simply incorrect. Material selection is not implicated in control of heterogeneities as is well-explained in the specification as originally filed. For example, merely selecting, for example, stainless steel, or nickel-titanium to deposit does not inherently control properties affected by the deposition process such as grain size, phase, composition, binding sites or strength. The teachings of Roth are entirely devoid of any teaching suggesting that heterogeneities in surfaces of the deposited material may be controlled in any predictable manner; the reference is wholly inappropriate as a §102(e) reference with respect to Claim 11.

Applicant submits, that the presently pending claims traverse the rejection under 35 U.S.C. §102(e) as being anticipated by Roth.

IV. The rejection of Claims 1, 4-6,8, 11-17 and 20-26 under 35 U.S.C. 102(e) over Reed, et al. (U.S. Patent No. 6,197,013) is inapplicable to the amended claims and should be withdrawn.

The rejection of claims 1, 4-6, 8, 11-17 and 20-26 under section 102(e) over Reed et al. should be withdrawn because it fails to disclose all the elements of the presently claimed invention. Since Reed et al. fails to disclose every element it cannot anticipate the present invention

Specifically, with regard to the amended pending claims 1, 4-6 and 8, Reed, et al fail to disclose an unpatterned, cylindrical metal substrate having a metal exterior surface, and depositing a stent-forming metal onto the metal exterior surface of the unpatterned cylindrical substrate, then defining the stent's structural elements in the deposited stent-forming metal. Rather, Reed, et al teach fabricating a cylindrical mandrel of silicon having a pattern silicon probes projecting from an exterior surface thereof, then coating the exterior surface of the cylindrical mandrel with a sacrificial layer of SiO_2, then depositing a conformal layer of metal. The stent lattice pattern may be made either by EDM or by selective deposition, presumably using a patterned photoresist and depositing the stent-forming metal through the photoresist onto

the patterned sacrificial layer covering the silicon substrate. (See, e.g., Col. 10, line 62 to Col 11, line 5).

In any reading of Reed, et al., it fails to disclose employing an unpatterned cylindrical metal mandrel having a metal exterior surface, depositing the stent-forming metal onto the metal exterior surface, then defining the pattern of the stent structural elements in the deposited stent metal, and then removing the substrate from the deposited and formed stent, as presently claimed.

Again, the Examiner's rejection of Claim 11 fails to address step (b), specifically the sub-step of controlling the formation of heterogeneities in surfaces of the biocompatible material during deposition. Accordingly, with regard to Claim 11, at least, the Examiner's §102(e) rejection is inappropriate.

With particular regard to the rejection of Claims 20-21 and 23-26 as being anticipated by Reed, et al., the Examiner cites to Col. 11, lines 39-52. Like Clubb, et al, however, this section of the Reed, et al disclosure merely teaches that other materials may be used, such as polyimides or biodegradable polymers may be used as carriers for the drugs to be delivered. This disclosure is wholly devoid of any teaching or suggestion that the heterogeneities in surfaces of the biocompatible material, itself, may be modulated in any controlled manner as claimed in the present application.

Based on all of the foregoing arguments, Applicants respectfully request the Examiner to withdraw the 35 U.S.C. §102 rejections based on the cited art.

V. The Provisional Rejection of Claims 14-23 for Obviousness-Type Double Patenting Over Claims 1-8 and 9-26 of Copending Application No. 09/745,304 is not ripe.

Applicants note the provisional rejection and, upon indication of allowable subject matter, will substantively address this provisional rejection. However, Applicant urges the Examiner to reconsider the provisional double patenting rejection in view of the amendments made to the claims. In particular, the amendments to Claims 1-8 and 10 are believed distinguish these claims from the subject matter claimed in the co-pending application. Moreover, the

subject matter of Claims 11-26 is submitted to be substantially distinct from the subject matter claimed in the co-pending application.

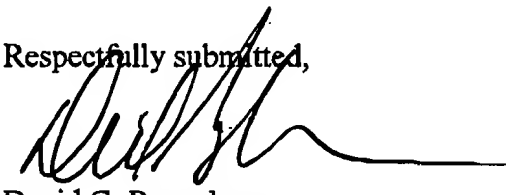
Summary

Applicants respectfully submit that the cited references fail to anticipate or render obvious the present invention and submit that pending claims, as amended, are allowable over the art cited and that of record

This Response is being concurrently filed with a Request for Continued Examination and is timely filed as it is being filed along with a one-month extension and appropriate fees.

Should the Examiner require any further information or wish to discuss any aspect of this Response, the Examiner is encouraged to telephone the undersigned at the telephone number set forth below.

Respectfully submitted,



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